UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,213	06/15/2001	Bengt E.B. Sandberg	33700WC004	5134

7590 03/29/2007

SMITH, GAMBRELL & RUSSELL, LLP
ATTORNEYS AT LAW
SUITE 800
1850 M STREET, N.W.
WASHINGTON, DC 20036

EXAMINER	
KANTAMNENI, SHOBHA	
ART UNIT	**PAPER NUMBER**
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/881,213	SANDBERG ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,7,9-11 and 22-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *1,3,4,7,9-11,22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/29/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/29/2007 has been entered.

Claims 1, 3, 4, 7, 9-11, and 22-24 are examined herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-4, 7, 9, 23-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific aromatic trifunctional crosslinking moieties with 1, 3, 5 substitution does not reasonably provide enablement for all moieties which would fall within the scope of the genus described by trifunctional crosslinking moieties. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without undue experimentation. Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1). The Nature of the Invention:

The rejected claim(s) is/are drawn to an invention which pertains to a method of conditioning utilizing compounds characterized by the formula found in claim 1 wherein the core (d) can be any aromatic compound with 1, 3, 5 substitution.

(2). Breadth of the Claims:

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass a method comprising the use of a compound comprising any aromatic compound with 1, 3, 5 substitution. The nature of the invention is complex in that it potentially encompasses any aromatic compound with 1, 3, 5 substitution, regardless of size, shape, etc.

(3). Guidance of the Specification:

The guidance given by the specification as to what types of aromatic compound with 1, 3, 5 substitution would be useful in a method of the instant invention is limited. Applicant discloses tri-substituted phenyl compounds as aromatic compound with 1, 3, 5 substitution useful in the instant invention. The specification does not teach that the scope of the invention is limited to these aromatic compounds with 1, 3, 5 substitution, however.

(4). Working Examples:

Applicant shows various tri-substituted phenyl compounds as trifunctional crosslinking moieties useful in the instant invention.

(5). State/Predictability of the Art.

The state of the art regarding trifunctional crosslinking moieties is advanced. It is noted, however, that any aromatic compound with 1, 3, 5 substitution compound capable of binding to three linkers as herein claimed would meet the claims. Accordingly, a tri-substituted anthracene, a tri-substituted indole could meet the limitations of the instant claims. Such large and obviously non-functional examples are not what renders the instant claims un-enabled, however. It is noted that Applicant goes to great lengths to describe the importance of the length of the linkers defined as a and b but does not similarly limit d. Accordingly, the state of the art regarding what core would be useful in the instant invention would be low. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved." See In re Fisher, 427 F.2d 833, 839 (1970). In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art cannot fully

describe the genus, visualize or recognize the identity of the members of the genus, by structure, formula, or chemical name, of the claimed subject matter. Hence, in the absence of fully recognizing the identity of the members of the genus herein, one of skill in the art would be unable to fully predict possible compounds operative in the method claimed.

(6). The quantity of Experimentation Necessary.

The skilled artisan would not be aware what type of aromatic compound with 1, 3, 5 substitution would be useful in the instant invention. For example at what size does the aromatic compound with 1, 3, 5 substitution become inoperable? Would a tri-substituted indole be useful? What about a tri-substituted anthracene? Does shape matter to the operability of the aromatic compound with 1, 3, 5 substitution? Applicant has only addressed working examples wherein the aromatic compound with is substituted 1,3,5 on the phenyl ring. Accordingly, the specification fails to provide sufficient support of the broad use of any group represented by " aromatic compound with 1, 3, 5 substitution." As a result, one of skill in the art would be forced to perform an exhaustive search for the embodiments of any compound having the d group recited in the instant claim suitable to practice the claimed invention. Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 4, 7, 9-11 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stayton et al. (USPN 6413934) in view of both Wilbur et al. (WO 97/291 14) and Ribi et al. (USPN 5491097).

Stayton et al. teaches streptavidin derivatives containing a biotin binding domain and a specific binding domain (i.e. a secondary functional domain), which binds a compound of interest, as useful for diagnostic purposes in devices such as vascular devices. The streptavidin derivatives are taught to be immobilized on a biotinylated substrate (via the biotin binding domain). The specific binding domain of the streptavidin derivative then captures the compound of interest. See col. 10, lines 23-67. Stayton et al. teaches that streptavidin derivatives were used, specifically, because they are known to be a powerful biotin-binding protein and that the ability to bind biotin tightly makes the biotin-streptavidin binding affinity essentially irreversible under normal physiological conditions (col. 1 , lines 18-33*, col. 3, lines 34-40).

Stayton et al. does not disclose a method using the compounds claimed, an extracorporeal device or that the biotin binding domain consists of avidin or streptavidin, specifically.

Wilbur et al. teaches the biotin containing compounds as instantly claimed (see, e.g., pp. 29-34). The compounds are taught to include a functional moiety useful for diagnostic purposes (Abstract). Linkers comprising hydroxyl functionalities are taught (p. 17, lines 20-23). Biotin sulfones are taught (p. 6, 3). The compounds are taught to comprise at least a biotin moiety and another moiety, which may be another biotin moiety, a reactive moiety or a functional moiety (p. 5, lines 18-20., p. 9, lines 14-24). For the trifunctional cross-linking moiety 5-amino-1, 3-dicarboxybenzene, see, e.g., p. 18, 23. For the linker 4,7, 10-trioxa-13-tridecanediamine and biotin as the binder, see, e.g., p. 31, 48. It is also taught that in the trimeric biotin compound comprising water soluble linker, the biotin moieities are at a distance that permit two of the biotin molecules to bind with one avidin or streptavidin. See page 31.

Ribi et al. teaches that biotin binding surfaces are known to be comprised of streptavidin and avidin (col. 7, lines 23-29).

It would have been obvious to one of ordinary skill in the art to replace the steps of (1) biotinylating the biotin binding domain of a diagnostic device and (2) binding the streptavidin derivative to the biotinylated substrate of Stayton et al. with the single step of biotinylating the biotin binding domain of a device with the biotin compounds of Wilbur et al. because (1) Stayton et al. and Wilbur et al. are both directed to inventions wherein biotin is connected to a second functional moiety', (2) the goal of Stayton et al. is to transform a biotin binding surface into a functionalized surface capable of capturing target compounds other than biotin; and (3) Wilbur et al. teaches a compound capable of binding to a biotin binding surface while also leaving a functional moiety free. One

would have been motivated to substitute the biotin-streptavidin complex of Stayton et al. with the compounds of Wilbur et al. because, as is shown by the teachings of Stayton et al. and Wilbur et al., the two are known in the art to be interchangeable agents comprising biotin on one side and a functionalized moiety on the other. Furthermore, one would have been motivated to substitute the complex of Stayton et al. with the compounds of Wilbur et al. because Stayton et al. teaches that the advantage of using streptavidin derivatives on a biotinlylated substrate is that streptavidin is known to have a strong affinity for biotin. Accordingly, it would be of a greater advantage to utilize a system wherein the interaction between the biotin and the functionalize moiety is actually achieved via covalent bonding. Finally, one would have been motivated to substitute the complex of Stayton et al. with the compounds of Wilbur et al. because doing so would reduce the number of steps required to functionalize the surface in the manner desired.

It would have been obvious to one of ordinary skill in the art to utilize a device wherein the biotin binding surface containing streptavidin or avidin as the biotin binding molecules because Ribi et al. teaches that it is known in the art to prepare biotin binding surfaces in such a manner. One would have been motivated to specifically utilize streptavidin or avidin as the biotin binding molecules because Stayton et al. teaches a biotin binding domain, generally, and a biotin binding domain comprising streptavidin or avidin molecules is within the scope of the genus taught by Stayton et al.

It is noted that the skilled artisan would recognize that a diagnostic device must, necessarily, be either extracorporeal or implanted and the skilled artisan would have

found it obvious to utilize the method of the combined references in either extracorporeal or implanted devices because Stayton et al. teaches diagnostic devices, generally.

It is further noted that the binding affinity of a molecule is a property of said molecule. Accordingly, since Wilbur et al. teaches the same compounds as instantly claimed, it is Examiner's position that, absent evidence to the contrary, the compounds will have the same binding affinities as instantly claimed, and the compounds taught by Wilbur et al. containing two biotins will be attached to the same avidin or streptavadin. A product and its properties are inseparable. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-4, 7, 9-11, 22-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

claims 1-26 of copending Application No. 10/311,150. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to a method for conditioning of a extracorporeal device for the extraction of toxic material from mammalian body fluids comprising passing a solution containing a reagent. The reagent, in the application '150 encompasses the reagent in the instant application. Therefore, the instant claims 1, 3-4, 7, 9-11, 22-24 are seen to be obvious over the claims 1-26 of application 10/311,150.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Tuesday, Thursday-Friday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D
Patent Examiner
Art Unit : 1617

SHEENI PADMANABHAN
SUPERVISORY PATENT EXAMINER